

Special 510k  
Korebalance Kinesthetic Ability Trainer  
SportKAT, LLC

## 510k Summary

APR 18 2007

**510k Owner:**  
SPORTKAT, LLC  
1497 Poinsettia Avenue, Suite 157  
Vista, CA 92083  
FDA Registration #: 2031091

**Contact:**  
Mr. Damon Lawson  
Cell (812) 212-2020  
Phone: (858) 866-3393  
FAX: (858) 866-3933

**Summary Date:** March 6, 2007

**Device Trade Name:** Korebalance™ Kinesthetic Ability Trainer  
**Common or Usual Name:** Apparatus, Vestibular Analysis (Computerized Postural Pressure Platform)  
**Classification:** Unclassified  
**Product Code:** LXV

**Predicate Device:** This Special 510k is for changes to the previously cleared K.A.T. 1000 device (K911795)

**Device Description:** The updated Korebalance™ Kinesthetic Ability Trainer device has the same intended use and incorporates the same balance board (platform) and bladder design technology as the originally cleared device. The modifications are primarily software based and allow:

1. Creation of a patient specific electronic record of patient information via a touchscreen GUI.
2. Quantitative measurement of patient balance performance while the patient executes a preprogrammed set of maneuvers or protocols with the board. The GUI provides instructions and visual feedback to the patient with regard to the maneuvers to be made and the success in executing the maneuver. The patient results are scored and saved (the information is not a clinical measurement but provides a reproducible quantitative measurement that the therapist can use to plan and monitor therapy) along with the bladder pressure measurement for use by the therapist, in conjunction with the therapist's observations, to assess patient progress over the course of multiple therapy sessions. Specific protocols are provided for vestibular training, orthopedic therapy, and falls prevention. These protocols are similar to those used with the previously cleared device.

3. Patients to play “games” displayed on the GUI that involve performing various maneuvers on the balance platform. Performance is scored. The games provide an additional means for the therapist to provide rehabilitation that is fun and challenging for patients.

**Indications for Use:** The Korebalance™ device is intended for use in balance therapy, only by health care professionals with experience in balance therapy. Patient suitability must be judged by the health professional on a case by case basis.

**Substantial Equivalence:** The modified device has the following similarities to the original previously cleared device:

- It has the same intended use
- It incorporates the same balance board and bladder design technology
- The degree of difficulty is adjustable
- The device provides a quantitative measure of performance

Modifications include the addition of a GUI, and a computer with software that allows the entry of patient specific information, the selection of static and dynamic preprogrammed tests, test selection and the measurement and the optional storage of patient performance information. The addition of modern 3-D games provides a means for patients to increase their balance board skills under the therapist’s guidance in an enjoyable manner. The changes do not materially alter the intended use or fundamental technology of the device, but serve to facilitate the provision of therapy, data collection and management.

**Testing:** The modifications to the existing device were made in accordance with the design control provisions of the quality system regulation and applicable guidance documents to show that the modified device is as safe, as effective, and performs as well as or better than the original device .



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 18 2007

SPORTKAT, LLC  
c/o Damon R. Lawson  
1497 Poinsettia Avenue, Suite 157  
Vista, CA 92083

Re: K070676  
Trade/Device Name: Korebalance Kinesthetic Ability Trainer  
Regulation Name: Vestibular Analysis Apparatus  
Regulatory Class: Unclassified  
Product Code: LXV  
Dated: March 5, 2007  
Received: March 19, 2007

Dear Mr. Lawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "MB Eydelman, M.D.", is written over the printed name.

Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose  
and Throat Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

Special 510k  
Korebalance Kinesthetic Ability Trainer  
SportKAT, LLC

### Indications for Use

510(k) Number (if known): K 0 7 0 6 7 6

Device Name: Korebalance™ (Kinesthetic Ability Trainer)

Indications for Use: The Korebalance™ device is intended for use in balance therapy, only by health care professionals with experience in balance therapy. Patient suitability must be judged by the health professional on a case by case basis.

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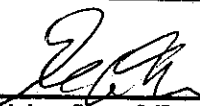
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription  
Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter  
Use \_\_\_\_\_

Prescription Use X  
(Per 21 CFR 801.109)

  
(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices

510(k) Number K 0 7 0 6 7 6